REMARKS

Applicants have amended claims 1, 7, 18, 20, and 26 as set forth above, however Applicants reserve the right to pursue the subject matter of the previous and original versions of the claims in a continuation application. No new matter has been added by way of these amendments. In view of these amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

The Office has objected to the amendment filed August 25, 2009 for allegedly introducing new material not supported by the original disclosure. The added material is asserted to be found in the disclosure on "page 4 lines 15-19, page 9 lines 8-10, and page 10 lines 1-20 [disclosing] that the first and second plunger members may be rotationally uncoupled or disengaged and states no where in the disclosure that the two are rotationally engaged." However, Applicants respectfully note the cited portions of the specification are original, have not been amended, and therefore can not constitute new matter.

The Office also alleges that "rotational engagement of the two plungers is not supported by the specification". However, Applicants respectfully note it is evident from the description and FIG. 2 in particular (which shows the uncoupled first and second plunger members) that at least in this embodiment, a bayonet coupling provides rotational engagement of the first and second plunger members when assembling the plunger. By definition, this is how a bayonet coupling works. The fact that other forms of coupling may be contemplated (e.g. the snap coupling referred to by the Office) does not negate the explicit disclosure of rotational coupling by the bayonet coupling. In Applicants' view, this disclosure, in combination with repeated disclosure of rotational uncoupling of the first and second plunger members provide ample disclosure to support embodiments with rotational engagement of the two plungers. Accordingly, the Office is respectfully requested to reconsider and withdraw this objection.

The Office has rejected claims 1-4, 6-10, and 13 under 35 U.S.C. 102(b) as allegedly being anticipated by U.S. Patent No. 5,114,404 to Paxton et al (Paxton). The Office asserts Paxton shows a plunger for a retractable syringe 20 having a spring (51 and/or 72) and a needle mount 58, said plunger comprising a first plunger member 20 and a second plunger member 76 that are capable of being releasably and rotationally engageable to co-operatively maintain said spring in an initial compressed state, arranged so that rotational disengagement (citing to col. 7, lines 43-67 and col. 8, lines 1-4) of said first plunger member and said

second plunger member can facilitate decompression of said spring from the initial compressed state when required to force retraction of said first plunger member and said needle mount when engaged therewith (citing to col. 7, lines 65-67) following depression of the plunger to deliver fluid contents of said syringe.

Paxton does not disclose or suggest a "plunger comprising a first plunger member and a second plunger member that are releasably engaged during withdrawal and depression of said plunger to co-operatively maintain said spring **in an initial compressed state**, arranged so that **rotational disengagement** of said first plunger member and said second plunger member can facilitate decompression of said spring from the initial compressed state when required to force retraction of said first plunger member and said needle mount when engaged therewith, following depression of said plunger to deliver fluid contents of said syringe" as recited by amended claim 1, or "a first plunger member and a second plunger member that are releasably engaged during withdrawal and depression of said plunger to co-operatively maintain said spring **in an initial compressed state** and are **rotationally disengageable** to facilitate decompression of said spring to force retraction of said first plunger member and said needle mount" as recited by amended claim 7.

The Office identifies plunger rod 20 of Paxton as the first plunger member of the rejected claims, small spring 72 as the initially compressed spring of the rejected claims and interlock 76 of Paxton as the second plunger member of the rejected claims. It is the Office's view that plunger rod 20 and interlock 76 co-operate to maintain small spring 72 in an initially compressed state until plunger rod 20 and interlock 76 are rotationally uncoupled to allow small spring 72 to decompress and retract needle 70. Applicants respectfully disagree with this reading of Paxton in relation to the rejected claims. It is clear from Paxton that plunger rod 20 is never rotationally disengaged from interlock 76. At best, plunger rod 20 engages and rotates lugs 69 on needle holder 58 which releases needle holder 58 from interlock 76 for retraction of needle holder 58 with needle 70 (See Paxton's FIG. 6 & 7 and column 7 line 60 to column 8 line 3.) This is not a "rotational disengagement of said first plunger member and said second plunger member" as claimed by Applicants as part of independent claim 1 and similarly in independent claim 7.

Furthermore, nowhere does Paxton describe a plunger comprising plunger rod 20 and interlock 76 as functional components of the plunger during withdrawal (i.e. to fill the syringe with fluid contents) and/or during depression (i.e. to deliver fluid contents).

Additionally, during this operation of Paxton's plunger, at no point is small spring 72 "initially" compressed by engagement between plunger rod 20 and interlock 76. It is only prior to withdrawal of plunger rod 20 that ratchet end cap 64 bears against interlock 76 (see FIG. 3) and then again at the end of delivery of the fluid contents of the Paxton syringe (see FIGS 5 and 6). Therefore, Paxton does not disclose or suggest a "plunger comprising a first plunger member and a second plunger member that are releasably engaged during withdrawal and depression of said plunger <u>to co-operatively maintain said spring **in an initial compressed state**</u>, arranged so that <u>**rotational disengagement**</u> of said first plunger member and said second plunger member can facilitate decompression of said spring from the initial compressed state when required to force retraction of said first plunger member and said needle mount when engaged therewith, following depression of said plunger to deliver fluid contents of said syringe" as claimed by Applicants as part of independent claim 1 and similarly for independent claim 7.

The Office has rejected claims 5 and 11-12 under 35 U.S.C. 103(a) as allegedly being unpatentable over Paxton, in view of U.S. Patent No. 5,211,628 to Marshall (Marshall), and further in view of U.S. Patent Application Publication No. 2003/0158525 to Thorley et al (Thorley). From a reading of the Office's detailed comments, it would appear that this rejection is based on Paxton and Marshall in combination, as Thorley has not been discussed. Applicants are responding on this basis.

The Office asserts that Paxton teaches a tooth and groove arrangement of the needle mount engagement (citing to col. 5, lines 35-40) but lacks barbed arms. The Office further asserts Marshall shows the needle mount engagement device comprises two barbed arms 56, and therefore asserts it would be obvious to modify Paxton to include two barbed arms.

Like Paxton, Marshall does not disclose or suggest the above-noted limitations of independent claims 1 and 7. Furthermore, neither Paxton nor Marshall disclose or suggest a plunger or retractable syringe "wherein the needle mount engagement device comprises two barbed arms" as recited by claims 5 and 11, respectively.

Marshall discloses a syringe having a plunger with a spring-loaded retractor that draws the needle into the plunger immediately after an injection is administered. Applicants respectfully disagree, however, that Marshall discloses two barbed arms (56) as

part of the needle-engaging portion of the plunger. According to Marshall, feature 56 is described as "enlarged head 56" of shaft 52 (See column 4 lines 67-69, and FIG. 1). Furthermore, enlarged head 56 is not part of a needle mount engagement device in Marshall. In the passage of Marshall that bridges columns 3 and 4, enlarged head 56 engages plunger upper wall 42, not the needle mount. Clearly, Marshall's enlarged head 56 does not anticipate or suggest a plunger or retractable syringe "wherein the needle mount engagement device comprises two barbed arms" as claimed by Applicants as part of claims 5 and 11.

The Office also argues that Marshall's recesses 36 are equivalent to the needle mount recesses of claim 12. However, Marshall does not disclose or suggest a retractable syringe "wherein the needle mount comprises recesses that are respectively engageable by the barbed arms" as recited by claim 12. As discussed above, the Office argues that Marshall's enlarged head 56 is actually the barbed arms. Even if Applicants were to agree with this, Marshall's recesses 36 are not engaged by enlarged head 56 (the alleged barbed arms). Therefore, Marshall does not disclose or suggest "wherein the needle mount comprises recesses that are respectively engageable by the barbed arms" as claimed by Applicants in claim 12.

The Office has rejected claims 14-19 under 35 U.S.C. 103(a) as allegedly being unpatentable over Paxton in view of Marshall. However, from the Office's detailed comments it would appear that Paxton and Thorley are actually cited against the patentability of claims 14-19, and that the Office only refers to Marshall (in combination with Thorley and Paxton) in relation to Claim 18. Applicants are responding on this basis.

With particular regard to claims 14-16, and 18, the Office asserts that Thorley describes a plunger disabling system where one or more projections are located on a collar which is mounted to the barrel (citing to ¶ 16). Furthermore, according to the Office, Thorley describes a pawl 422A (i.e. one or more projections) that engages a respective step on the plunger. According to the Office, it would be obvious to modify the syringe of Paxton to include a collar that comprises two pawls that engage respective steps on the first plunger member to co-operably prevent subsequent depression of the first plunger member following retraction of the needle mount and thereby prevent syringe re-use.

Like Paxton and Marshall, Thorley does not disclose or suggest the above-noted limitations for independent claims 1 and 7. Furthermore, it does not make sense to

combine the teachings of Paxton, Marshall, and Thorley to suggest "a collar mounted to the barrel" as recited by claim 14, "wherein said collar comprises one or more projections capable of co-operating with one or more abutments of said first plunger member to form a plunger disabling device" as recited by claim 15, "wherein the first plunger member comprises steps, and wherein the one or more projections comprise two pawls that are engageable with respective steps on said first plunger member to co-operably prevent subsequent depression of said first plunger member" as recited by claim 16, or "a collar mounted to the barrel and comprising two ribs and two pawls", "a first plunger member having two steps and two ledges", "and wherein said two pawls are engageable with respective steps on said first plunger member to co-operatively prevent subsequent withdrawal of said first plunger member following retraction of the needle mount and a needle" as recited by independent claim 18.

Applicants submit the collar, one or more projections, and abutment described by Thorley would not make a sensible or workable combination with the plunger or syringe of Paxton. As is clear from Thorley at paragraphs [0066] to [0076] and in FIGS 11-14, the disabling system requires successive 90° rotations of the plunger so that the projection 422A and abutment 475 are engageable only following needle retraction and not beforehand. The Paxton plunger does not rotate by 90°, let alone by successive 90° rotations. Applicants therefore submit that to modify Paxton based on Thorley would require substantial and inventive input from a person of ordinary skill in the art. In fact, the difficulties encountered by the skilled person would be so significant that the skilled person would not expect to succeed in creating a workable plunger and syringe.

With regard to Claim 17, the Office argues that based on the rib 422B and ledge 474 of Thorley, it would be obvious to modify the syringe of Paxton to include a collar that comprises two ribs that engage respective steps on the first plunger member to co-operably prevent subsequent depression of the first plunger member following retraction of the needle mount and thereby prevent syringe re-use.

It does not make sense to combine the teachings of Paxton, Marshall, and Thorley to suggest "wherein the first plunger member comprises ledges, and wherein the one or more projections comprise two ribs that are engageable with respective ledges on said first plunger member to co-operably prevent subsequent withdrawal of said first plunger member following retraction of the needle mount" as recited by claim 17.

Applicants again refer to Thorley at paragraphs [0066] to [0076] and in FIGS 11-14, where the disabling system requires successive 90° rotations of the plunger so that the projection 422B and ledge 474 are engageable only following needle retraction and not beforehand. The Paxton plunger does not rotate by 90°, let alone by successive 90° rotations. Applicants therefore submit that to modify Paxton based on Thorley would require substantial and inventive input from a person of ordinary skill in the art. In fact, the difficulties encountered by the skilled person would be so significant that the skilled person would not expect to succeed in creating a workable plunger and syringe.

The Office has rejected claims 20-36 under 35 U.S.C. 103(a) as allegedly being unpatentable over Paxton. The only explanation given by the Office for this rejection is "Based on the disclosure of Paxton it would be obvious to one skilled in the art to use the method described in claim[s] 20-[36] in order to assemble the syringe in a functional manner."

While Paxton's disclosure may teach one skilled in the art to assemble a syringe in a functional manner, Paxton's syringe is different than Applicants' claimed syringe. Correspondingly, the functionality disclosed in Paxton does not include a step for "releasably engaging a first plunger member and a second plunger member so that during withdrawal and depression of said plunger, the first plunger member and the second plunger member cooperatively maintain a spring in an initial compressed state" as claimed by Applicants as part of independent claims 20 and 26 for similar reasons to those already discussed.

Accordingly, in view of the foregoing amendments and remarks, the Office is respectfully requested to reconsider and withdraw the rejections of independent claims 1, 7, 18, 20, and 26. Since claims 1-6, 8-17, 19, 21-25, and 27-36 depend from claims 1, 7, 18, 20, and 26, respectively, they are distinguishable over the cited references and patentable for at least the same reasons.

In view of all of the foregoing, Applicants submit that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

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